6,808,534. B1

JAN 19 2005

PTO/SB/21 (04-04)
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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	10/023,027
Filing Date	12/17/2001
First Named Inventor	Arnold M. Escano
Art Unit	3738
Examiner Name	Javier G. Blanco
Total Number of Pages in This Submission: 17	Attorney Docket Number: ENDOV-51640

ENCLOSURES *(check all that apply)*

- [X] Fee Transmittal Form
- [X] Fee Attached
- [ ] Amendment / Reply
- [ ] After Final
- [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Response to Missing Parts/ Incomplete Application
- [ ] Response to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
- [ ] After Allowance communication to Technology Center (TC)
- [ ] Appeal Communication to Board of Appeals and Interferences
- [ ] Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
- [ ] Proprietary Information
- [ ] Status Letter
- [X] Other Enclosure(s) *(please identify below)*:

Postcard; Request for Certificate of Correction

Remarks

CUSTOMER NO. 24201

Certificate JAN 27 2005 of Correction

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	John V. Hanley FULWIDER PATTON LEE & UTECHT, LLP
Signature	John V. Hanley
Date	1/4/2005

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria,VA 22313-1450 on the date shown below:

Typed or printed name	John V. Hanley		
Signature	John V. Hanley	Date	1/4/2005

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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28 JAN 2005

Doc Code:

PTO/SB/17 (12-04v2)
Approved for use through 07/31/2006. OMB 0651-0032
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Effective on 12/08/2004.
Fees pursuant to the Consolidated Appropriatons Act, 2005 (H.R. 4818).

FEE TRANSMITTAL for FY 2005

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT	($)	$100.00

Complete if Known	
Application Number	10/023,027
Filing Date	12/17/2001
First Named Inventor	Arnold M. Escano
Examiner Name	Javier G. Blanco
Art Unit	3738
Attorney Docket No.	ENDOV-51640

METHOD OF PAYMENT (check all that apply)

☒ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☒ Deposit Account Deposit Account Number: 06-2425 Deposit Account Name: Fulwider Patton

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, except for the filing fee

☒ Charge any additional fee(s) or any underpayment of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments

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FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

	FILING FEES		SEARCH FEES		EXAMINATION FEES		
		Small Entity		Small Entity		Small Entity	
Application Type	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fees Paid($)
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee ($)	Small Entity Fee ($)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

Total Claims		Extra Claims	Fee ($)		Fee Paid ($)
_____	- 20 or HP =	_____	x $50.00	=	$0.00

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims		Extra Claims	Fee ($)		Fee Paid ($)
_____	- 3 or HP =	_____	x $200.00	=	$0.00

HP = highest number of independent claims paid for, if greater than 3.

Multiple Dependent Claims	Fee ($)	Fee Paid ($)
	_____	_____

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listing under 37 CFR 1.52(e)), the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets		Extra Sheets		Number of each additional 50 or fraction thereof	Fee ($)	Fee Paid ($)
_____	- 100 =	_____	/ 50	_____ (round up to a whole number)	x $250.00	= $0.00

4. OTHER FEE(S)

	Fee Paid ($)
Non-English specification, $130 fee (no small entity discount)	
Other (e.g. late filing surcharge): Certificate of Correction	$100.00

SUBMITTED BY

Signature		Registration No. (Attorney/Agent)	38,171	Telephone	310-824-5555
Name (Print/Type)	John V. Hanley			Date	1/4/2005

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

28 JAN 2005

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of

ARNOLD M. ESCANO

Patent No.: 6,808,534 B1

Issued: October 26, 2004

Serial No: 10/023,027

Filed: December 17, 2001

For: COLLAPSIBLE JACKET GUARD

Examiner: Javier G. Blanco

Group Art Unit: 3738

Client ID/Matter No: ENDOV 51640

January 4, 2005
Los Angeles, California 90045

REQUEST FOR CERTIFICATE OF CORRECTION

Certificate of Correction Department
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The above-identified patent has been found to have the errors set forth in the enclosed Certificate of Correction. It is requested that this Certificate of Correction be issued and returned to us. Since these errors occurred in both the final printing phase of the patent and in the final application, a check in the amount of $100.00 is enclosed to cover the necessary fees. Should the Office determine that additional fees are needed, please charge Deposit Account No. 06-2425.

01/24/2005 MAHMED1 00000081 6808534
01 FC:1811 100.00 OP

The errors are verifiable in the patent application file as follows:

ERROR	APPLICATION FILE
Column 3, line 40, after "vasculature." continue with "In one embodiment," (not a new paragraph).	Application filed on December 17, 2001. See Attachment A, page 5.
Column 5, line 66, delete "a traumatic" and insert --atraumatic--.	Application filed on December 17, 2001. See Attachment A, page 9.
Column 6, line 52, after "systems" insert a dash.	Application filed on December 17, 2001. See Attachment A, page 10.
Column 7, line 31, before "Fig. 5B" delete "is".	Application filed on December 17, 2001. See Attachment A, page 12.
Column 9, line 52, after "such that the" delete "a".	Applicant error.
Column 10, line 18, delete "the to" and insert --to--.	Applicant error.
Column 12, line 33, delete "operate" and insert --operates--.	Applicant error.
Column 12, line 35, delete "endoprosthesis" and insert --endoprostheses--.	Applicant error.
Column 12, line 36, delete "preventing" and insert --prevents--.	Applicant error.
Column 12, line 50, delete "it's" and insert --its--.	Applicant error.
Column 15, line 64, delete "20.7French" and insert --20.7 French--.	Application filed on December 17, 2001. See Attachment A, page 27.
Column 16, line 57, delete "maybe" and insert --may be--.	Application filed on December 17, 2001. See Attachment A, page 29.

ERROR	APPLICATION FILE
Column 24, line 67, after "member" insert --,-- (a comma).	Examiner's Amendment of August 29, 2003. See Attachment B.

These errors occurred in good faith and correction thereof does not involve such changes in the patent as would constitute new matter or would require re-examination. It is requested that a Certificate of Correction be issued and returned to us.

Attached hereto, in duplicate, is Form PTO-1050, with at least one copy being suitable for printing.

A duplicate of this document is attached.

Respectfully submitted,

FULWIDER PATTON LEE & UTECHT, LLP

By: _____
John V. Hanley
Registration No. 38,171

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75368-1

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of

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A duplicate of this document is attached.

Respectfully submitted,

FULWIDER PATTON LEE & UTECHT, LLP

By: _____
John V. Hanley
Registration No. 38,171

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75368-1

the patients vasculature, will not cause further complications during the deployment of the graft prosthesis, and will be fairly easy to use and manipulate by an operating physician. The present invention as described herein fulfills these and other needs.

SUMMARY OF THE INVENTION

Briefly and in general terms, the present invention is directed towards repairing vasculature. More particularly, the present invention includes a system that is configured to accomplish intraluminal repair of defects such as aneurysms found in blood vessels.

In one aspect, the system of the present invention includes a catheter for intraluminally delivering an endovascular device at a target site within vasculature. In one embodiment, the catheter includes a jacket guard configured to provide the system with an enhanced atraumatic profile.

In other aspects, the present invention embodies an intraluminal delivery system for securing a prosthesis within the vessels of the corporeal lumen of an animal, such as a human. The preferred embodiment of a placement system is configured for introducing a graft into a corporeal lumen and positioning the graft in the area of the aortic bifurcation. The delivery system embodies a main catheter capable of containing the prosthesis and placement system for intraluminal delivery. A significant improvement of this system is the use of a main catheter having a smaller diameter from the prior art systems. Another significant improvement is the introduction of a pliable jacket guard located slightly proximal to an expandable member on the main catheter for assisting in the smooth delivery and deployment of a graft prosthesis. The jacket guard which may embody various different forms protects the vessel during delivery of the system by providing a buffer against trauma.

In general, the present invention provides an intraluminal grafting system and method which improves upon the prior art systems. One feature that impacts the capability of any intraluminal device or delivery system is the size of the system's

independently translated. It is used to pull the ipsilateral inferior member back into the ipsilateral iliac artery, and correctly position it therein.

Preferably, the delivery system includes a balloon catheter assembly capable of expanding the attachment system of the superior member of the graft. Expanding the system in this manner urges the outwardly disposed members, if present, into the wall of the aorta which is one method of securely fastening the system thereto. The balloon catheter assembly further includes a pliable jacket guard located slightly proximal to the expandable member. The jacket guard provides for atraumatic delivery of the system during placement and deployment of the attachment system of the superior member of the graft. Preferably, the balloon catheter has a multilumen catheter shaft. At least one of these lumens allows the inflation of the balloon. Others house the delivery system for the ipsilateral extremity, the release wire for the ipsilateral self-expanding attachment system, and the main guidewire. Preferably, the release wire is also housed within a small diameter cylinder which allows the balloon catheter to be advanced and retracted relative to the release wire.

The main guidewire extends distally beyond the remainder of the system. The main guidewire also extends proximally throughout the system and out of a control device such that its proximal end can be manipulated by the physician. In this manner the main guidewire may be advanced to a desired location and aid in the manipulation of the remainder of the system. Such a guidewire may be of a configuration typical to prior art procedures, or may be specifically designed for use in a reduced diameter delivery system.

The ipsilateral lower extremity of the graft is deployed into the ipsilateral iliac artery by retracting the ipsilateral release wire. The physician has independent control of the ipsilateral release wire which may be pulled proximally with respect to the remainder of the system. By pulling the ipsilateral release wire proximally it is unfastened from the members of the ipsilateral attachment system and the ipsilateral lower extremity. This allows the ipsilateral attachment system to expand toward the

wall of the artery. The ipsilateral release wire and cylinder may then be removed from the patient and the system.

Optionally, once the ipsilateral attachment of the ipsilateral lower extremity is expanded, further securing of the attachment system may be accomplished by positioning the expandable member of the balloon catheter over the expanded ipsilateral attachment system and expanding the expandable member to further expand and engage the ipsilateral attachment system into the vessel wall. This optional procedure is assisted by the pliable jacket guard located slightly proximal of the expandable member. During the positioning of the balloon catheter over the ipsilateral attachment system, the balloon catheter is moved proximally within the partially deployed graft device. This proximal movement of the balloon catheter may cause the partially deployed graft to be buckled or snagged thereby resulting in either dislodgement of the partially deployed graft or at the least, trauma to the vessel wall.

Beneficially, the pliable jacket guard of the present invention reduces the likelihood that the balloon catheter may snag on the graft walls by providing a soft smooth transitional edge surface at the proximal end of the jacket guard. Therefore, it will be appreciated that the jacket guard will improve the safety as well as assist in the delivery of the graft system and the deployment of the graft attachment systems – both the superior attachment system and the ipsilateral attachment system.

Once the contralateral lower extremity is correctly positioned into the contralateral iliac artery, it may be deployed in much the same way as the ipsilateral lower extremity. The contralateral positioning system has various possible configurations. All of the configurations allow for the contralateral release wire to be pulled proximally with respect to the remainder of the system and unfastened from the contralateral extremity and contralateral attachment system. Once the contralateral release wire is withdrawn and the contralateral attachment system deployed, the remainder of the contralateral system may be removed from the patient and the system.

The remaining components of the system may be withdrawn from the patient at any time the components are free from the others. This leaves the graft in

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a partial cross-sectional view, depicting a bifurcated graft implanted in the aortic bifurcation of a human;

FIG. 2 is an enlarged partial cross-sectional view, depicting the present invention jacket guard located at a distal end of the delivery system configured for intraluminal delivery;

FIG. 3 is a plan view, depicting the delivery system;

FIG. 4A is an enlarged partial cross-sectional view, depicting a first embodiment of the present invention jacket guard;

FIG. 4B is an enlarged partial cross-sectional view, depicting a delivery catheter as used in conjunction with the embodiment of FIG. 4A;

FIG. 5A is an enlarged cross-sectional view, depicting a second embodiment of the present invention wherein the expandable member is configured for use as a jacket guard;

FIG. 5B is an enlarged partial cross-sectional plan view, depicting a delivery catheter as used in conjunction with the embodiment of FIG. 5A;

FIG. 6 is an enlarged partial cross-sectional plan view, depicting a first embodiment of the grafting system with the bifurcated graft partially deployed;

FIG. 7 is an enlarged partial cross-sectional plan view, depicting a second embodiment of the grafting system with the bifurcated graft partially deployed;

leading edge 121 of the catheter ring 120 may be encompassed within an overlapping region 166 of a jacket guard 160 that protects the vessel walls from such leading edge 121 and promotes smooth motion within the vasculature. The main delivery catheter 23 forms the primary delivery vessel or container of the grafting system 20 in that the majority of the components of the graft 24 are located within the main delivery catheter 23 while being delivered to the aorta.

The main catheter assembly 22 provides protection for both the grafting system components and the blood vessels. One novel feature of the main delivery catheter 23 and catheter ring 120 used in this invention is the reduced diameter of the main catheter assembly 22 capable of delivering a complete bifurcated grafting system. The simplified delivery systems and attachment systems are notable features which allow this reduced diameter. The use of a main catheter assembly 22 measuring 20.7 French in diameter has been demonstrated effectively. Several delivery systems conforming to this specification were built each having a main catheter assembly 22 with a 20.7 French diameter. The innovations of this invention, including a pliable jacket guard 160, permit the use of a catheter assembly approximately as small as 20 French in diameter to deliver a complete aortic bifurcation grafting system. This reduced diameter for delivery of a bifurcated graft greatly eases the procedure of implanting the graft. A smaller diameter delivery device reduces the stress to the patient's system, easing healing and recovery.

The French scale is used in the medical field to measure the diameter of blood vessels and medical equipment for delivery into blood vessels. One French equals one-third of a millimeter or approximately .013 inches. (3F = 1 mm). Therefore, 20.7 French = 6.9 mm or approximately .272 inches in diameter.

The intraluminal grafting system 20 is delivered via this reduced diameter main catheter assembly 22. Although portions of the balloon catheter assembly 26, such as the expandable member 30 and the jacket guard 160, and main guidewire 42 extend distally from the distal end of the main catheter assembly, the bulk of those components reside therein during delivery. Generally, the components

pulled through the first cylinder 38. Near its distal end the first cylinder 38 has a plurality of portals 124 which access an inner lumen 126 of the cylinder 38. These portals 124 permit the ipsilateral release wire 112 to be threaded between the first cylinder 38, the ipsilateral attachment system 78 and the ipsilateral inferior member 32. To facilitate this connection the balloon catheter shaft 28 has at least one cutaway 128 which allows the ipsilateral release wire to pass between the cylinder (on the interior of the balloon catheter shaft) and the bifurcated graft (on the exterior balloon catheter shaft). The cutaway 128 may be elongated so that relative motion between the cylinder and the balloon catheter assembly is not hindered by the ipsilateral release wire 112. The first cylinder 38 may consist of a relatively rigid thin-walled tube formed of a suitable biocompatible material such as stainless steel. The first cylinder 38 must have an inner lumen sufficiently large enough to contain the ipsilateral release wire 112.

The ipsilateral release wire 112 may be formed from nitinol. The purpose of the ipsilateral release wire is to keep the ipsilateral attachment system 78 from deploying until the bifurcated graft 24 is properly positioned with the ipsilateral inferior member 32 located within the ipsilateral iliac artery. The ipsilateral release wire 112 may be releasably attached over or around the self-expanding ipsilateral attachment system 78 and the ipsilateral inferior member 32 to prevent the ipsilateral attachment system 78 from expanding. As the ipsilateral release wire 112 is pulled proximally, it is detached from the attachment system 78 and releases the self-expanding attachment system 78 which expands the ipsilateral inferior member and secures it to the wall of the iliac artery.

replaced 9/

In addition, it may be desirable to further secure the attachment system 78 after it has expanded onto the wall of the iliac artery. The balloon catheter assembly 26 may be retracted proximally such that the expandable member 30 is positioned at the expanded attachment system 78. Once positioned the expandable member 30 may be inflated to further expand the attachment system against the vessel wall thereby tightly securing the wall engaging members 74 into the vessel wall. During the retraction of the balloon catheter assembly 26 to the target site, the pliable

DETAILED ACTION

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. John V. Hanley on June 8, 2004.

In claim 1, line 10, "graft" has been replaced by --device--.

In claim 20, line 9, "graft" has been replaced by --device--.

In claim 24, line 5, a comma (--,--) has been after "member".

In claim 27, line 4, --an elongate shaft,-- has been added after "having".

In claim 27, line 4, --pliable-- has been added in front of "jacket".

In claim 27, lines 6-7, "the delivery system including an elongate shaft" have been deleted.

The above revisions were made in order to correct minor formalities.

PTO/SB/ 44 (07-03)
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UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

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DATED : October 26, 2004

INVENTOR(S) : Arnold M. Escano

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